## SCIENTIFIC EVIDENCE SUPPORTS ANTHRAX VACCINATION

A commentary by Meryl Nass that describes anthrax vaccination as unsafe and ineffective<sup>1</sup> repeats assertions made by the author in previous settings,<sup>2-3</sup> assertions that have been considered and dismissed by multiple government experts and civilian scientific committees.<sup>4-5</sup> Critically, it neglects a recent review by the Institute of Medicine (IOM) of the scientific evidence for the safety and effectiveness of this vaccine.<sup>4</sup>

Thoughtful readers will appreciate the scrutiny applied by the IOM in its review. Not surprisingly, the institute gives more weight to cohort studies than to case reports. Regarding the vaccine's effectiveness, the IOM review states,

... the available evidence from studies with humans and animals, coupled with reasonable assumptions of analogy, shows that AVA [anthrax vaccine adsorbed] as licensed is an effective vaccine for the protection of humans

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against anthrax, including inhalational anthrax, caused by all known or plausible engineered strains of  $B.\ anthracis.^{4(p10)}$ 

As to the safety of the anthrax vaccine, the review has this to say:

The committee found no evidence that people face an increased risk of experiencing life-threatening or permanently disabling adverse events immediately after receiving AVA, when compared with the general population. Nor did it find any convincing evidence that people face elevated risk of developing adverse health effects over the longer term, although data are limited in this regard (as they are for all vaccines). 4(p2)

The *Lancet* quotes IOM Committee to Assess the Safety and Efficacy of the Anthrax Vaccine chariman Brian Strom as saying, "If we had a bias to begin with, it probably was against the military. I felt we just had to turn over the right stone and we'd find a smoking gun out there. But we didn't find it, and we looked hard."

The commentary omits several useful facts. Every lot of anthrax vaccine used in the United States met US Food and Drug Administration (FDA) lot-release specifications, both before and after the FDA's January 2002 approval of the manufacturer's renovations. The FDA quality-control requirements specified in 1999, before the anthrax vaccine shortage developed, were the same requirements met in 2002. In addition, a May 2001 trial of an Air Force physician who disobeyed his commanding officer by refusing vaccination began with 1.5 days of testimony by Nass, testimony that the judge eventually ruled as having no material value to the jury.

Anthrax vaccine is a safe and effective vaccine, in the considered opinions of America's most accomplished scientists. The scientific evidence to support this finding appears in the IOM report for all to read.

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